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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/798,579 | 03/12/2004 | Kazuko Shinozaki | 081356-0210 | 6471 |
| 22428 | 7590 | 07/17/2008 | EXAMINER | |
| FOLEY AND LARDNER LLP | | | KUMAR, VINOD | |
| SUITE 500 | | | ART UNIT | PAPER NUMBER |
| 3000 K STREET NW | | | | 1638 |
| WASHINGTON, DC 20007 | | | MAIL DATE | DELIVERY MODE |
| | | | 07/17/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 10/798,579 | Applicant(s) SHINOZAKI ET AL. |
| | Examiner VINOD KUMAR | Art Unit 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 April 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4,6,9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4,6,9,14 and 15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/136/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on March 25, 2008 and April 14, 2008 are entered.

Status of objections and rejections

2. Claims 1, 4, 6, 9, 11 and 12-15 are pending.
3. Claims 2-3, 5, 7-8, and 10 are cancelled.
4. Claims 11-13 have been withdrawn from examination.
5. Claims 1, 4, 6, 9 and 14-15 are examined on merits in this Office action.
6. Objections to claims 4 and 9 are withdrawn in light of claim amendment filed in the paper of March 25, 2008.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/restriction

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Claim Objections

9. Claim 1 is objected to because of the following informalities:

Claim 1 is objected for reciting "(i)" in line 13, and "(ii)" in line 16. These recitations should be deleted.

Claim Rejections - 35 USC § 112

10. Claims 4 and 9 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant with improved propagation efficiency of scions, improved propagation efficiency and rooting efficiency of scions or improved propagation efficiency of scions and prolonged vase life of cut flowers, and a method of producing said transgenic plant, comprising transformation of a plant with a DNA sequence encoding the DREB1A protein of SEQ ID NO: 2, does not reasonably provide enablement for a DNA sequence having 94% sequence identity to SEQ ID NO: 1. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed on November 27, 2007. Applicant traverses the rejection in the paper filed on March 25, 2008.

Applicant argues that sequence alignment disclosed in the drawings and the guidance provided in the specification is adequate to indicate to one skilled in the art which amino acid residue must be changed without abrogating protein function (response, page 6, lines 19-26).

Applicant's arguments are fully considered but are deemed to be unpersuasive.

Claims 4 and 9 are directed to a nucleotide sequence having 94% sequence identity to SEQ ID NO: 1, which would encompass encoded proteins having unspecified amino acid changes compared to SEQ ID NO: 2. An 94% sequence identity to instant SEQ ID NO: 1 of 933 nucleotides in length, and comprising 648 nucleotides of coding sequence would encompass encoded proteins having 71% sequence identity to instant SEQ ID NO: 2.

It is maintained that the specification does not provide guidance on using nucleotide sequences encoding proteins having 71% sequence identity to SEQ ID NO: 2, in a method of producing transgenic plants with improved characteristics as instantly claimed.

It is further maintained that making amino acid changes in SEQ ID NO: 2 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate

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only relatively conservative substitutions or no substitutions. See Keskin et al., Thornton et al. and Guo et al. as discussed in previous Office actions. It is further maintained that neither the state of art nor Applicants provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. The additions, deletions or substitutions in one or more amino acid residues would also encompass changes in the functionally important domain(s) of the encoded protein. In the absence of guidance, it would have been highly unpredictable at the time the claimed invention was made that a DNA sequence having 94% sequence identity to SEQ ID NO: 1, could have been used in a method of producing a transgenic plant with improved rooting efficiency and/or prolonged vase life.

In the absence of adequate guidance, it is maintained that undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use a DNA sequence having 94% sequence identity to SEQ ID NO: 1, in a method of producing a transgenic plant exhibiting improved rooting efficiency and/or prolonged vase life. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed previously and further outlined above, it is maintained that undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to practice the invention commensurate in scope

with these claims.

Accordingly, the rejection is maintained.

11. Claims 4 and 9 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed on November 27, 2007. Applicant traverses the rejection in the paper filed on March 25, 2008.

Applicant argues that the DNA and amino acid sequences of DREB family members are aligned in the drawings. Applicant cites pages 23-25 of the specification to support the argument (pages 6-7, paragraph bridging pages 6 and 7).

Applicant's arguments are fully considered but are deemed to be unpersuasive.

It is maintained that the essential feature of claims 4 and 9 is a DNA consisting of a nucleotide sequence having at least 94% sequence identity to SEQ ID NO: 1.

The specification describes increased salt tolerance and improved rooting efficiency and prolonged vase life of SEQ ID NO: 1 encoding DREB1A protein of SEQ ID NO: 2. See pages 41-46, Examples 1-4, Tables 1- 4.

Applicant is reminded that a 94% sequence identity to instant SEQ ID NO: 1 of 933 nucleotides in length would encompass 55 substitutions in SEQ ID NO: 1. This would correspond to 55 amino acid substitutions in 216 amino acid long protein of SEQ

ID NO: 2, implying that the claims would encompass proteins having about 71% identity to SEQ ID NO: 2.

The specification does not describe the structure for said sequences and thus their function is unknown.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of DREB1A protein of SEQ ID NO: 2.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

See *in re Curtis* (69 USPQ2d 1274 (Fed. Cir. 2004)), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not

predict the operability of other species other than the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would "instantly recall" additional species of the genus already "stored" in the minds, but if other members of the genus would not "naturally occur" to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office action, the requirement for written description has not been met.

12. Claims 1, 4, 6, 9 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "subjecting regenerants to a selection for said characteristics" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for subjecting the regenerants to selection processes to select transformed plants with improved propagation efficiency of scions, improved propagation efficiency and rooting efficiency of scions or improved propagation efficiency of scions and prolonged vase life of cut flowers. This does not comply with written description requirements. The specification also fails to provide support for the full scope of instantly claimed phrase "subjecting regenerants to a selection for said characteristics". Thus, such a phrase constitutes **NEW MATTER**. In response to this

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rejection, Applicant is required to point to support for the phrase "subjecting regenerants to a selection for said characteristics" or to cancel the new matter.

Dependent claims 4, 6, 9 and 14-15 are also rejected because they fail to overcome the deficiency of claim 1.

Claim Rejections - 35 USC § 102

13. Claims 1, 4, 6, 9 and 14-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al. (Nature Biotechnology, vol. 17, pp. 287-291, March 1999) for the reasons of record stated in the Office action mailed on November 27, 2008. Applicant traverses the rejection in the paper filed on March 25, 2008.

Applicant argues that Kasuga et al. do not teach the selection step of improved propagation efficiency of scions, improved propagation efficiency and rooting efficiency of scions or improved propagation efficiency of scions and prolonged vase life of cut flowers. Applicant further argues that Exhibit A (a photograph of *Arabidopsis* having flowers) is a fragile plant that has no value as an ornamental plant, and thus Kasuga et al. transformed *Arabidopsis* plant cannot anticipate the claimed invention (response, page 7, lines 16-31).

Applicant's arguments are fully considered but are not found to be persuasive.

Applicant is reminded that the characteristics "improved propagation efficiency of scions, improved propagation efficiency and rooting efficiency of scions or improved propagation efficiency of scions and prolonged vase life of cut flowers" are inherent properties of SEQ ID NO: 2 expression in the transformed plant.

Applicant is also reminded that *Arabidopsis* is an important model plant system where use of grafting and scions have been extensively used to study long distance signaling mechanisms. See for example, Turnbull et al. (*The Plant Journal*, 32:255-262, 2002; see in particular, abstract). Applicant is also reminded that instantly claimed transformed plant and a method of making said plant reads on any plant species including *Arabidopsis*.

It is, therefore, maintained that Kasuga et al. disclose a transgenic plant and a method of making said transgenic plant comprising transformation of said plant with an expression vector comprising stress-inducible rd29A promoter operably linked to drive expression of a nucleotide sequence (100% sequence identity to instant DREB1A DNA or SEQ ID NO: 1) encoding stress-inducible and the DNA binding protein of DREB1A (SEQ ID NO: 2), wherein said DREB1A protein binds to a stress-responsive element of a stress-inducible promoter in response to environmental stresses like, freezing, drought or salt. The reference further discloses a recombinant vector, stress (drought, salt or freezing) tolerant transgenic plant and a method of producing said transgenic plant comprising said stress-inducible promoter operably linked with a stress inducible coding region of *Arabidopsis CBF3* (a DREB transcription factor). The transgenic plants exhibited increased tolerance to salt and drought (dehydration) stresses. See in particular, page 287, abstract; page 288, Figures 1 and 2; page 289, Figures 3-5; page 290, Table 1; 1st and 2nd columns of page 290; page 291, experimental protocol. It may be emphasized that DREB1A DNA used in Kasuga et al. has 100% sequence identity to instant SEQ ID NO: 1 which encodes a protein having 100% sequence identity to

instant SEQ ID NO: 2. This is also cited in Kasuga et al. (see in particular, page 287, 2nd paragraph, right column).

It is also maintained that the property of improved propagation efficiency of scions, improved propagation efficiency and rooting efficiency of scions or improved propagation efficiency of scions and prolonged vase life of cut flowers would be inherent to the method of producing a transformed plant comprising expression of DREB1A (SEQ ID NO: 2) in said plant.

Applicants are also reminded that when the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed to be operable or enabling. See *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

It is important to note that something which is old does not become patentable upon the discovery of a new property. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.

Also see *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of

preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates"). Furthermore, see *Integra LifeSciences I Ltd. v. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, Kasuga et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

14. Claim 15 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Kasuga et al. (*Nature Biotechnology*, vol. 17, pp. 287-291, March 1999; Applicant's IDS) in view of Applicants' admitted stated of the prior art, Dalton et al. (*Plant Science*, 132:31-43, 1998) for the reasons of record stated in the Office action mailed on November 27, 2008. Applicant traverses the rejection in the paper filed on March 25, 2008.

Applicant argues that Dalton et al. fail to compensate for the deficiencies of Kasuga et al., and thus the combined teachings of the cited art fail to render claim 15 obvious (response, page 8, lines 9-12).

Applicant's arguments are fully considered but are deemed to be unpersuasive for the reasons as discussed above.

It thus maintained that Kasuga et al. teach a transgenic plant and a method of making said transgenic plant comprising transformation of said plant with an expression vector comprising stress-inducible rd29A promoter operably linked to drive expression of a nucleotide sequence (100% sequence identity to instant DREB1A DNA or SEQ ID NO: 1) encoding stress-inducible and the DNA binding protein of DREB1A (SEQ ID NO: 2), wherein said DREB1A binds to a stress-responsive element of a stress-inducible promoter in response to environmental stresses like, freezing, drought or salt. The reference further teaches a recombinant vector, stress (drought, salt or freezing) tolerant transgenic plant and a method of producing said transgenic plant comprising said stress-inducible promoter operably linked with a stress inducible coding region of *Arabidopsis CBF3* (a DREB transcription factor). See in particular, page 287, abstract; page 288, Figures 1 and 2; page 289, Figures 3-5; page 290, Table 1; 1st and 2nd columns of page 290; page 291, experimental protocol.

Kasuga et al. do not teach silicon carbide whisker-mediated plant transformation.

Applicants' admitted state of the prior art teaches use of silicon-carbide whisker in plant transformation. See in particular, page 32, right column.

It is thus maintained that it would have been obvious to use any method of plant transformation that were well known in the prior art as admitted by the Applicants (see page 38, 3rd paragraph) including using the cited Dalton et al. silicon-carbide whisker based plant transformation method to arrive at the claimed invention with a reasonable expectation of success.

Accordingly, it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

15. Claims 1, 4, 6, 9 and 14-15 remain rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Examiner, Art Unit 1638